1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Hydrocortisone Sodium Succinate for Injection
Trade Name: Solu-Cortef; HYDROCORTISON
Synonyms: Hydrocortisone sodium succinate Powder For Solution For Injection or Infusion, IM/IV
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:
EU Indication of danger: Toxic to Reproduction: Category 3
EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child
May form combustible dust concentrations in air

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

100 MG PLAIN
SAFETY DATA SHEET

Material Name: Hydrocortisone Sodium Succinate for Injection
Revision date: 01-Nov-2014
Version: 2.1

Other Hazards
Australian Hazard Classification (NOHSC):


Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>125-04-2</td>
<td>204-725-5</td>
<td>Repr.Cat.3;R63</td>
<td>Repr. 2 (H361d)</td>
<td>91.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium phosphate, monobasic</td>
<td>7558-80-7</td>
<td>231-449-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>7558-79-4</td>
<td>231-448-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
- * Proprietary
- Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
- In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:  For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure:  None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:  None

5. FIRE FIGHTING MEASURES

Extinguishing Media:  Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:  Carbon dioxide, carbon monoxide

Fire / Explosion Hazards:  Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:  Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills:  Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:  Store as directed by product packaging.

Specific end use(s):  No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrocortisone Sodium Succinate

Pfizer OEL TWA-8 Hr: 100µg/m³, Skin

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Powder</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>White to off-white</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

Hydrocortisone Sodium Succinate

No data available

Sodium phosphate, dibasic

No data available

Sodium phosphate, monobasic

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under recommended storage conditions. Solutions are unstable after 4 hours.
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Exposure to light
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause slight irritation. May cause skin irritation. (based on components). May be absorbed through the skin in harmful amounts. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. However, occupational handling of this product is not expected to result in relevant exposures.

Known Clinical Effects: Effects on vision have been seen during clinical use. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension). Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>5000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>5000mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD 50</td>
<td>449mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD 50</td>
<td>&gt;500mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>150mg/kg</td>
</tr>
</tbody>
</table>

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Hydrocortisone Sodium Succinate
Eye Irritation Rabbit Minimal

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrocortisone Sodium Succinate

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 Day(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>140 mg/kg/day</td>
<td>LOAEL</td>
<td>Thymus</td>
</tr>
<tr>
<td>4 Day(s)</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>100 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>11 Day(s)</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>62 mg/kg/day</td>
<td>LOAEL</td>
<td>Endocrine system</td>
</tr>
<tr>
<td>2 Week(s)</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>560 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver, Bone Marrow</td>
</tr>
<tr>
<td>85 Day(s)</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>175 mg/kg/day</td>
<td>LOAEL</td>
<td>Adrenal gland</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydrocortisone Sodium Succinate
Reproductive & Fertility-Females  Rat  Oral  210 mg/kg/day  LOAEL  Maternal toxicity
Embryo / Fetal Development  Mouse  Oral  10 mg/kg/day  LOAEL  Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Hydrocortisone Sodium Succinate
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo In Vitro Direct DNA Damage  Rat, Mouse  Positive
In Vivo In Vitro Chromosome Aberration  Rat, Mouse  Positive
Cytogenetics  Mouse  Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
SAFETY DATA SHEET

Material Name: Hydrocortisone Sodium Succinate for Injection
Revision date: 01-Nov-2014
Version: 2.1

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Hydrocortisone Sodium Succinate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 204-725-5

Sodium phosphate, monobasic
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-449-2

Sodium phosphate, dibasic
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb, 2270 kg
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-448-7

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3

R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.